National Committee on Vital and Health Statistics
Advising the HHS Secretary on National Health Information Policy

Update: Recommendations for Immediate Action on ICD-11

Subcommittee on Standards

September 9, 2021

NCVHS Charges Related to ICD-11

- The National Committee on Vital and Health Statistics (NCVHS) is the advisory body on health data, statistics, privacy and national health information policy.

- One key role for NCVHS is to monitor the continued effectiveness of adopted health data standards pursuant to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

- This includes making recommendations regarding preparing for adoption of the International Classification of Diseases, Version 11 (ICD-11) in the United States.

Purpose

- Our purpose is to recommend timely action to enable the U.S. to make informed decisions regarding adoption of ICD-11.

- Because of delays resulting from the pandemic and the change in administration, NCVHS is updating our recommendations to HHS submitted on November 25, 2019, regarding the need for research and a strategic communications plan specific to ICD-11.

Committee Process

- NIH/NLM researchers attended NCVHS' expert roundtable meeting leading up to development of initial Committee recommendations (Kin-Wah Fung, Olivier Bodenreider, Julia Xu).
- NCVHS invited Dr. Fung to present on his most recent research at the spring meeting of the full Committee (March 2021).
- Informed by this new information, the Standards Subcommittee developed updated recommendations for consideration by the full Committee.

Recommendations

We propose the following three updated recommendations:

1. HHS should conduct research to evaluate the impact of different approaches to the transition to and implementation of ICD-11.

2. HHS should conduct outreach and communicate regularly to the U.S. healthcare industry about the ICD transition.

3. HHS should examine how to best enable blanket access to ICD-11 and subsequent updates that could minimize costs to the industry.

Background

- The ICD is a classification system developed by the World Health Organization (WHO) to serve as the foundation for identifying health trends and statistics worldwide and is the international standard for reporting mortality and morbidity and other conditions affecting health.
- The WHO published ICD-11 for review in 2018 and the World Health Assembly formally adopted this version on May 25, 2019, to be effective beginning January 1, 2022.
- WHO plans to discontinue maintenance of ICD-10.

ICD-11 adoption by the United States has three distinct dimensions:

1. **Adoption for mortality reporting.**

   Mortality (cause of death) reporting is a condition of U.S. membership in the WHO contributing to worldwide surveillance. The WHO agreement is a U.N. treaty with implementation obligations led by the National Center for Health Statistics (NCHS) in conjunction with state vital registration and statistics agencies.

   - Presentation on changes from ICD-10 to ICD-11: https://ncvhs.hhs.gov/wp-content/uploads/2020/01/Presentation-Changes-from-ICD-10-to-ICD-11-Pickett-Anderson.pdf

2. **Adoption for morbidity reporting for health care and public health systems.**

   Morbidity (diseases, disorders, injuries and other health conditions) reporting is used for international public health surveillance and statistical reporting. The ICD coding system also supports: administration; quality assessment and research; public health surveillance to monitor the incidence and prevalence of diseases; capture of data for safety and quality guidelines; and state health data reporting.

ICD-11 adoption by the United States has three distinct dimensions:

3. Adoption for U.S. health care payments.

The ICD-11 morbidity classification is a HIPAA-designated medical code set, which is an essential component of all hospital and physician billing and payment processes for Medicare, Medicaid and private insurance payers, among others. HHS regulations make its use for morbidity coding mandatory for hospitals, physician practices, and other health care provider and service settings.

Learn from the Past

- The U.S. implemented the previous classification system, ICD-10, for mortality reporting in 1999 and for morbidity in 2015.
- This was 25 years after it was endorsed by the WHO.
- A protracted regulatory process made the U.S. the very last country to implement ICD-10 for morbidity reporting among industrialized nations.
- The on-again, off-again regulatory implementation deadlines caused unnecessary costs and wasteful re-work throughout the health care system.

Why Implement ICD-11?

ICD-11 is designed as a digitally curated system that takes advantage of modern information technology and automation.

It holds promise for reducing the cost of implementation and includes other potential benefits which could:

- provide flexibility to eliminate the need for a clinical modification (CM)*
- enable continuous updates, thus eliminating the need for future versions, e.g. ICD-12
- improve coordination with other classifications and terminologies
- improve comparability of mappings and language translations
- support online services

* A clinical modification is a country-specific supplemental coding system. It is WHO's expectation that the structure of ICD-11 negates the need for separate clinical modifications.

Rationale for NCVHS's Recommendation 1:

Recommendation 1: HHS should conduct research to evaluate the impact of different approaches to the transition to and implementation of ICD-11.

- Implementation and use of ICD-11, and the extent to which it can be automated in real-world settings in the U.S., requires research and evaluation.
- The need for research is compelling given ICD-11 may, or may not, provide significant opportunity to reduce provider burden and increase interoperability of electronic health information – high priority goals for the U.S.
- The Committee believes it is urgent that HHS conduct research to evaluate the impact of different approaches to the transition and implementation of ICD-11 in the U.S. for morbidity classification.

Rationale for NCVHS's Recommendation 1 continued:

Recommendation 1

The Committee recommends the following actions to evaluate the impact (in order of importance):

1. Assess whether ICD-11 can fully support morbidity classification in the U.S. without development of a U.S. CM.
2. Demonstrate how ICD-11 could help with tracking and understanding of worldwide COVID pandemic variants (and future pandemics) through use of standard codes over the long-term. Research would inform whether these kinds of assertions are true.
3. Assess the quality of ICD-11 mappings to other adopted clinical and administrative code sets.
4. How would ICD-11 support EHRs across different provider settings, e.g., ambulatory, inpatient etc., including the impact of the changes in code structure in different environments.
5. Provide insight into the potential for industry-wide efficiencies from leveraging the ICD-11 digital capabilities.

Rationale for NCVHS's Recommendation 1 continued:

- NCVHS recommends that HHS complete this research within the next 12 months because key questions regarding timely adoption and implementation will depend on the findings.

- Completing the needed studies in this timeframe will require the immediate allocation of federal attention and resources.

Current Research

- Only 3 studies directly compare ICD-11 with ICD-10-CM.
- Austin et al compared ICD-11 and ICD-10-CM regarding the capture of adverse events in relation to quality measurement and safety.
- Fung et al completed two studies. The first was a study that compared the coverage of ICD-10-CM and ICD-11 in 6 disease areas.
- In the second study, this was expanded to include:
  - A first systematic and comprehensive comparison of the ICD-10-CM and ICD-11
  - Recoding of a representative sample of frequently used ICD-10-CM codes, using post coordination when necessary and performed independently by 2 expert terminologists
  - Exhaustive analysis of the reason why full representation cannot be achieved
  - Review of coding guidance to identify differences in code meaning
  - Assessment of the overall feasibility of replacing ICD-10-CM with ICD-11 in morbidity coding.

Updated Research Questions for HHS to Evaluate ICD-11 Implementation for the U.S.

Due to the paucity of research in the area of evaluation of ICD-11 for implementation in the U.S., the Committee developed the following revised recommendations:

1. Evaluate ICD-11 on burden, efficiency, workflow, training and implications for documentation quality by use case and stakeholder (cost and benefits and human factors).
2. Evaluate the adherence of ICD-11 to accepted terminology practices, especially regarding maintenance, such as concept permanence, non-ambiguity, maintaining consistency and backward compatibility.
3. Evaluate alternative approaches (methods & infrastructure platforms) to support semantic comparability studies.
4. Evaluate technical and legal considerations, e.g., issues including validation of received ICD-11 value sets, and how systems implementation guides (IGs) can accommodate the 10-digit vs 11-digit codes in ICD-11.
5. Identify the extent to which ICD-11 coordinates with detailed clinical documentation using nationally mandated clinical information interoperability content standards.
6. Identify the extent to which ICD-11 coordinates with non- clinical national and state mandated information interoperability content standards.

Updated Research Questions for HHS to Evaluate ICD-11 Implementation for the U.S.

7. Assess the impact of adding pre-coordinated codes to ICD-11 that corresponds to a concept previously represented with post-coordinated codes?
8. Evaluate fitness of ICD-11 for morbidity to contribute to convergence of clinical, social, and administrative health information standards.
9. Assess whether ICD coding can be implemented as a computable service on top of standardized clinical statements captured by the EHR using the Promoting Interoperability Standards to record clinical care?
10. Assess whether interoperable representations of research and clinical terms/classification and nosology simplify distribution and deployment of health terminology and vocabulary standards.

Rationale for NCVHS's Recommendation 2:

Recommendation 2: HHS should conduct outreach and communicate regularly to the U.S. health care industry about the ICD transition.

- Large-scale change requires effective communication.
- Lessons learned from the last ICD transition point to the need for consistent and accurate messaging from a single, trusted source.
- The Committee is recommending the development of a communications plan with strategic messaging to ensure a proactive, cost-effective and efficient transition.

Rationale for NCVHS's Recommendation 2 (continued):

Recommendation 2

The Committee recommends that the messages focus on the following national needs:

- Encourage all stakeholders to commence planning for how they will address the anticipated implementation.
- Provide education on how ICD-11 is designed to work with EHRs and operate in an electronic world.
- Demonstrate that the U.S. is conducting research to evaluate ICD-11 for use in the U.S.
- Determine the costs and benefits of implementation and inform decisions about the best path forward.
- Ensure that the industry understands that the decision to implement ICD-11 would be a federal mandate.
- Retain the U.S. leadership role in major worldwide health initiatives.

Rationale for NCVHS's Recommendation 2 (continued):

- NCVHS also recommends that HHS execute a strategic communications plan as early as possible, preferably running parallel with the recommended research work over the next 12 months.

- Recommendations for this communication plan were developed with significant stakeholder input during the NCVHS August 2019 expert roundtable meeting.

Rationale for NCVHS's Recommendation 3:

Recommendation 3: HHS should examine how to best enable blanket access to ICD-11 and subsequent updates that could minimize costs to the industry.

- The WHO has developed and retains all rights to ICD-11 and its ICD-11 software.
- It is important for the U.S. to negotiate an agreement that ensures blanket access to ICD-11, subsequent updates, and future modifications.
- Such an agreement will make the code set available at no cost for everyone in the U.S., including individuals who download their health data.

Conclusion

- NCVHS believes that taking a proactive approach to ICD-11 is essential.
- This should include research, communications, licensing and copyright as described in the Committee's initial recommendations.
- Implementing these recommendations will enable the U.S. to identify a path forward that supports national health care priorities, optimizes benefits, and minimizes cost.
- Our purpose is to recommend timely action to enable the U.S. to make informed decisions regarding adoption of ICD-11.
- Because of delays resulting from the pandemic and the change in administration, NCVHS is updating our recommendations to HHS submitted on November 25, 2019, regarding the need for research and a strategic communications plan specific to ICD-11.

Questions & Discussion